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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/085,888	Applicant(s) CARLEBACH ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a non-final Office action. The allowability of claims 26-46 has regretfully been withdrawn in view of newly cited prior art US Patent No. 6,216,023 to Holte and/or in view of 35 U.S.C. 101. Rejections based on this reference follow.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 26 and 44 each recite the limitation "a breath receiver in fluid communication with a subject" on line 3 of claim 26 and on line 3 of claim 44. In this case, the subject or human being is non-statutory subject matter and cannot be claimed positively. See MPEP 2105. The line should be replaced with "a breath receiver adapted to be placed in fluid communication with a subject" in order to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

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application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 27, 39-42, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,216,023 to Holte. Holte teaches an apparatus for computerized breath analysis comprising a breath receiver in fluid communication with a subject (col. 5, lines 55-58 of Holte). A breath analyzer is coupled to the receiver that analyzes at least one breath of the subject (col. 5, lines 57-65 of Holte). The apparatus provides an indication of the discrepancy between the end tidal partial pressure in the breath of the subject and the arterial carbon dioxide partial pressure of the subject (col. 6, lines 15-46 of Holte).

The applicants should note that the following language is merely "intended use" language:

"is utilized to provide an indication of the arterial carbon dioxide partial pressure of the subject" on lines 2-3 of claim 27,

"wherein said at least one non-respiratory measurement made on the subject is utilized to provide said indication of the arterial carbon dioxide partial pressure of the subject" on lines 3-5 of claim 40,

" said information is used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject" on lines 4 and 5 of claim 41,

and " such that said information is used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject" on lines 4-5 of claim 42. Such language cannot be relied upon to overcome the prior art of Holte, since the reference discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. None of the cited

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language adds structural limitation to the claim. Furthermore, either the discrepancy or the non-respiratory measurement made on the subject of Holte is certainly capable of being used to provide an indication of arterial carbon dioxide partial pressure of the subject. Similarly, either of the information about the condition of the blood circulation or the information about the content of the blood can certainly be used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject. If the applicants were to incorporate language positively reciting that the analyzer or another structural part of the apparatus accomplishes the uses identified above, the limitations would no longer be interpreted as "intended use" language and the claims would furthermore be allowable, as long as they are also rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims

Regarding claims 39-42, an input 212 receives at least one non-respiratory measurement made on the subject (col. 5, lines 1-4 of Holte), and the at least one non-respiratory measurement made on the subject is utilized to provide said indication of the discrepancy between the end tidal carbon dioxide partial pressure in breath of the subject and the arterial carbon dioxide partial pressure of the subject (col. 6, line 15-31 of Holte). With further regard to claims 41 and 42, the carbon dioxide arterial partial pressure value entered at input 212 provides information both about the condition of blood circulation and the content of the blood.

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Regarding claim 46, the apparatus utilizes the output of the breath analyzer to provide the indication of the discrepancy (col. 5, lines 58-65; col. 6, lines 15-31 of Holte).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28, 37-42, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,927,670 to Turney et al. in view of US Patent No. 6,216,023 to Holte. Turney disclose an apparatus for computerized breath analysis for use in an intensive care unit (col. 2, lines 19-20 of Turney) comprising a breath receiver 28-30 in fluid communication with a subject (fig. 3; col. 2, lines 61-66 of Turney). A breath analyzer 26, 40, 44, 52 is coupled to the receiver 28-30 (figs. 2 & 3; col. 2, lines 26-50; col. 3, lines 1-2 of Turney). The breath analyzer 26, 44 comprises a carbon dioxide analyzer and an oxygen analyzer (col. 2, lines 38-50 of Turney). Turney lacks the apparatus providing an indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure.

However, Holte teaches an apparatus for computerized breath analysis comprising a breath receiver in fluid communication with a subject (col. 5, lines 55-58 of Holte). A breath analyzer is coupled to the receiver which analyzes at

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least one breath of the subject (col. 5, lines 57-65 of Holte). The apparatus provides an indication of the discrepancy between the end tidal partial pressure in the breath of the subject and the arterial carbon dioxide partial pressure of the subject (col. 6, lines 15-46 of Holte). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Holte with that of Turney in order to provide early indication or warning of serious physiological conditions in an intensive care unit (col. 1, lines 30-42 of Holte).

The applicants should note that the following language is merely "intended use" language:

"is utilized to provide an indication of the arterial carbon dioxide partial pressure of the subject" on lines 2-3 of claim 27,

"wherein respiratory volume measured by said meter is utilized to provide said indication of the arterial carbon dioxide partial pressure of the subject" on lines 3-5 of claim 37,

"wherein said flow rate information is utilized to provide said indication of the arterial carbon dioxide partial pressure of the subject" on lines 3-5 of claim 38,

"wherein said at least one non-respiratory measurement made on the subject is utilized to provide said indication of the arterial carbon dioxide partial pressure of the subject" on lines 3-5 of claim 40,

"said information is used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject" on lines 4 and 5 of claim 41,

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and " such that said information is used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject" on lines 4-5 of claim 42. Such language cannot be relied upon to overcome the prior art of Turney in view of Holte, since the reference discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. None of the cited language adds structural limitation to the claim. Furthermore, any one of the discrepancy, the volume, the flow rate, or the non-respiratory measurement made on the subject of Holte is certainly capable of being used to provide an indication of arterial carbon dioxide partial pressure of the subject. Similarly, either of the information about the condition of the blood circulation or the information about the content of the blood can certainly be used to correlate transfer of arterial carbon dioxide from the blood to the exhaled breath of the subject. If the applicants were to incorporate language positively reciting that the analyzer or another structural part of the apparatus accomplishes the uses identified above, the limitations would no longer be interpreted as "intended use" language and the claims would furthermore be allowable, as long as they are also rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims

Regarding claims 37 and 38, the apparatus comprise a pulmonary volume meter 52 (fig. 3; col. 2, lines 43-47; col. 4, lines 29-34 of Turney), wherein a spirometer is an instrument that measures the volume of air entering and leaving the lungs and wherein the meter is disclosed as providing flow rate information.

Regarding claims 39-42, an input 212 receives at least one non-respiratory measurement made on the subject (col. 5, lines 1-4 of Holte), and the at least one non-respiratory measurement made on the subject is utilized to provide said indication of the discrepancy between the end tidal carbon dioxide partial pressure in breath of the subject and the arterial carbon dioxide partial pressure of the subject (col. 6, line 15-31 of Holte). With further regard to claims 41 and 42, the carbon dioxide arterial partial pressure value entered at input 212 provides information both about the condition of blood circulation and the content of the blood.

Regarding claim 46, the apparatus utilizes the output of the breath analyzer to provide the indication of the discrepancy (col. 5, lines 58-65; col. 6, lines 15-31 of Holte).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holte, as applied to claims 26, 27, 39, and 46 above, and further in view of US Patent No. 4,463,764 to Anderson et al. Holte is silent as to how the breath analyzer determines the end tidal carbon dioxide partial pressure measurement from the breath sample. However, Anderson discloses an apparatus for computerized breath analysis that determines the end tidal carbon dioxide partial pressure measurement from a breath sample by analysis of at least one breath waveform (col. 3, lines 57-65; col. 4, lines 40-43 and lines 65-69; col. 5, lines 16-30; col. 8, lines 24-31 of Anderson). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the breath analyzer of Anderson as that of Holte, since Holte discloses using a breath analyzer

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capable of determining the end tidal partial pressure of a subject, and Anderson describes and appropriate such analyzer.

Allowable Subject Matter

Claim 29-32, 34-36, and 43-45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 29, 30, 32, and 34, the prior art of record fails to teach or fairly suggest an apparatus for computerized breath analysis wherein the computational unit utilizes the difference between values of inspired and expired oxygen partial pressure in at least one breath of a subject to provide the indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure of the subject, in combination with all of the other limitations of the claim.

With regard to claim 31, the prior art of record fails to teach or fairly suggest an apparatus for computerized breath analysis wherein the respiration diagnosis generator provides an indication of the respiratory status of the subject based on the indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure of the subject, in combination with all of the other limitations of the claim.

With regard to claims 35 and 36, the prior art of record fails to teach or fairly suggest an apparatus for computerized breath analysis wherein either the

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respiratory volume or the flow rate information measured by the pulmonary volume meter is utilized to provide the indication of the discrepancy between the end tidal carbon dioxide partial pressure in breath of a subject and the arterial carbon dioxide partial pressure of the subject, the indication being provided by the apparatus, in combination with all of the other limitations of the claim.

With regard to claim 43 the prior art of record fails to teach or fairly suggest an apparatus for computerized breath analysis wherein the at least non-respiratory measurement made on the subject and utilized by the apparatus to provide an indication of the discrepancy between the end tidal carbon dioxide partial pressure in the breath of the subject and the arterial carbon dioxide partial pressure of the subject comprises at least one of an ECG measurement, pulse rate measurement, pulse oximetric measurement of arterial oxygen saturation level, cardiac output measurement or body temperature measurement, in combination with all of the other limitations of the claim.

With regard to claims 44 and 45, the prior art of record fails to teach or fairly suggest an apparatus for computerized breath analysis wherein the respiration diagnosis generator provides a diagnostic determination of the respiratory state of the subject based on at least one waveform output parameter from the capnographic interpreter unit and at least one non-respiratory measurement, in combination with all of the other limitations of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is

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(571) 272-4729. The examiner can normally be reached on Monday-Friday
10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the
examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The
fax phone number for the organization where this application or proceeding is
assigned is 703-872-9306.

Information regarding the status of an application may be obtained from
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free).

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